Amendments to the Claims:

Please cancel Claims 3 and 12-18.

Please add new Claims 19, 20 and 21.

The Claim Listing below will replace all prior versions of the claims in the application:

Claim Listing:

1. (Original) A method of increasing systemic bioavailability of a hormone administered by inhalation comprising:

administering to the respiratory system of a patient or animal in need of said hormone aerodynamically light particles that have a mass mean diameter greater than 5 μm, an aerodynamic diameter less than 4.7 μm and that include said hormone,

wherein the particles are delivered and deposited to the patient's or animal's lungs and the hormone is released in the patient's or animal's blood stream for at least 4 hours.

2. (Original) The method of Claim 1 wherein the hormone is insulin.

3. (Canceled)

4. (Original) The method of Claim 1 wherein the particles further include a biodegradable material.

5. (Original) The method of Claim 1 wherein the mass mean diameter is greater than 10 μm.

6. (Original) The method of Claim 1 wherein the mass mean diameter is greater than 20 μm.

7. (Original) The method of Claim 1 wherein the hormone is released in the patient's or animal's blood stream for at least 10 hours.

8. (Original) The method of Claim 1 wherein the hormone is released in the patient's or animal's blood stream for at least 24 hours.

9. (Original) The method of Claim 1 wherein the hormone is released in the patient's or animal's blood stream for at least 48 hours.

10. (Original) A method of delivering a hormone to the pulmonary system to a patient or animal, comprising:

administering, via inhalation, particles that include a hormone and a biodegradable material, have an aerodynamic diameter less than about 4.7 μm and a mass mean diameter greater than about 5 μm,

wherein the hormone is delivered and deposited in the patient's or animal's lungs and is released in the patient's or animal's blood stream for at least 4 hours.

11. (Currently amended) A method of increasing the ~~bioavailabilty~~ bioavailability of a hormone, comprising:

administering to a patient or animal, via inhalation, particles that include a hormone and a biodegradable material, have an aerodynamic diameter less than about 4.7 μm and a mass mean diameter greater than about 5 μm,

wherein the hormone is delivered and deposited in the patient's or animal's lungs and is released in the patient's or animal's blood stream for at least 4 hours.

12-18. (Canceled)

19. (New) The particles of Claim 1, further comprising a tap density less than about 0.4 g/cm^3.

20. (New) The particles of Claim 10, further comprising a tap density less than about 0.4 g/cm^3.

21. (New) The particles of Claim 11, further comprising a tap density less than about 0.4 g/cm^3.

Claims 1-2 and 4-11 remain pending in the application. The non-elected claims have been canceled.

Rejections under judicially created doctrine of obviousness-type double patenting

Examiner has rejected several sets of Claims over co-owned U.S. Patents. To overcome the following rejections, Applicants will filed the appropriate Terminal Disclaimers. A copy of an unexecuted Terminal Disclaimer is enclosed herewith. Once executed, this will be forwarded to the Examiner.

Claims 1 and 4-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 16-17 of US Patent 5, 874,064.

Claims 1,2,4,7-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 17, 20, and 27 of US Patent 5, 855,913.

Claims 1,2, and 4-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 18-20,23 and 26 of US Patent 6,436,443.

Claims 1,2, 4,5,7-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 1-16 and 22 of US Patent 5,985,309.

Claims 1,2, 4 and 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 16, 20-21 of US Patent 6,503,480.

Claims 1,2, 4 -11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 15-16 and 26-27 of US Patent 6,254,854.

Upon the filing of the executed Terminal Disclaimer, these rejections will be rendered moot.

Claims Rejections – 35 USC § 103

The Examiner has rejected Claims 1,2 and 4-11 under 35 USC § 103 (a) as being unpatentable over Platz et al. (USPN 6,423,344 B1). The Examiner states that Platz teaches methods of delivering therapeutic agents such as insulin along with pharmaceutical carriers and excipients to the lung of a patient particles having a mass mean diameter of less than 10 microns and particles having a diameter of 0.4- 5 microns,

A close reading of Platz ('344 patent) is necessary to determine the actual scope of its teachings. Platz' stated purpose is to produce the desired size range without having to further separate (e.g, size classify) the particles prior to packaging. (Col. 4, line 4-5)

Platz admits that "it can be difficult to control particle size and particle size distribution in compositions produced by spray drying. For pulmonary delivery, it is critical that the average particle size be maintained below 5μm, preferably in the range from 0.4 μm to 5 μm, and that the amount of the composition comprising particles outside of the target size range be minimized." (Col. 2, line 42-48)

Although Platz *does* mention compositions having a particle size below 10 μm (Col. 6, line 5) Pltaz makes clear that there is a delicate balance of size, rugosity and moisture content (Co.l 6, line 5-17). Size alone will not satisfy Platz' problem of controlling the powders so they can be handled efficiently. Platz repeatedly states that the desired size range, i.e., below 5 μm, and prefereably in the range from 0.4 μm to 5 μm. (e.g Col.4, line 15)

Further, the Examples indicate just how important the desired size range, i.e., below 5 μm, is for the invention of Platz. As can be seen, none of the powders produced in any of the spray drying runs come close to size claimed in the instant invention of greater than 5μm.

Table	MMD Size in μm	% less than 5μm
Table 2	1.8	100
Table 2	1.4	100
Table 2	1.6	100
Table 2	1.4	100
Table 3	2.41	100
Table 3	2.69	82.3
Table 3	2.43	100
Table 4	1.34	100

The actual teachings of Platz are limited to the preparation of particles under controlled conditions. To give Platz credit for more than the production of the powders without his having even shown that they can be delivered to the lung (let alone be made bioavailable) goes far beyond what he actually discloses. For the Examiner to do so, would be using hindsight reconstruction using the Applicants own teachings which is not permissible. The claims of the instant invention disclose a method of increasing systemic bioavailability of a hormone administered by inhalation comprising aerodynamically light particles having a *mass mean diameters greater than 5μm*, a stated aerodynamic diameter wherein the particles are delivered and deposited to the lung and the *hormone is release in the blood stream for at least 4 hours.* There is nothing in Platz that teaches such a release profile. Indeed, as the powders of Platz were never delivered, there is no information about any release profile. In fact, as explained in detail above, Platz teaches away from the instant invention.

In summary, none of the Platz '344 examples describe particles characterized by the parameters of the present invention, that is, (1) a mass mean diameter (MMD) greater than 5 microns (μm); and (2) an aerodynamic diameter (MMAD) less than 4.7 microns and (3) wherein the hormone is delivered and deposited in the blood stream for at least 4 hours. Further, Platz does not teach that such a particle composition has superior properties for pulmonary delivery. Most importantly, Platz did not actually deliver his powders. Thus, it is unclear whether indeed his powders were actually capable of being delivered as claimed. However, even if the Platz powders were delivered there is absolutely no teaching or suggestion that the particles would